

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MONTVALE SURGICAL CENTER a/s/o
T.S.,

Plaintiffs(s),

v.

AETNA INSURANCE COMPANY; ABC
CORP. (1-10) (Said names being fictitious
and unknown entities),

Defendant(s),

CIVIL ACTION NO.: 12-2874-SDW-MCA

CIVIL ACTION

PLAINTIFFS' BRIEF IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT

On the Brief and Of Counsel:

Andrew R. Bronsnick, Esq.

PRELIMINARY STATEMENT

Plaintiff, Montvale Surgical Center, under an assignment of benefits from T.S. and through their undersigned counsel, submit this memorandum of law in opposition to the Motion for Summary Judgment (the “Motion”) submitted by defendant Aetna Insurance Company (“Aetna”). For the reasons set forth below, the Court should deny the Motion in its entirety.

Plaintiff, an ambulatory surgical center and an out-of-network healthcare medical provider, asserts the right to recover payment for a medical procedure known as a Platelet Rich Plasma Injection or “PRP.” The PRP was performed on T.S.’s right shoulder. Defendant’s Memorandum of Law in Support of Motion for Summary Judgment, Exhibit E, Operative Reports.

The gravamen of the Complaint is that Aetna has failed to pay the Plaintiff for a medically necessary procedure. By denying coverage for PRP injections on the grounds that the procedure is supposedly “experimental”, Aetna never addressed whether the procedure was medically necessary under the circumstances. Complaint ¶13. The Complaint alleges that Aetna did not provide a proper response to the appeals submitted by the Plaintiff and did not provide an explanation for its determinations. In addition, Aetna never provided a copy of the Summary Plan Description to the Plaintiff despite their request for same. The Complaint further alleges that there exists ample literature validating the efficacy of PRP injections; therefore they are not classified as experimental/investigational. Complaint ¶12. In short, Aetna adopted a blanket policy of requiring that patients and their treatment providers undergo an arduous appeal process when, in reality, Aetna has preordained that it will deny coverage for certain medical procedures. As such, the appeal process is futile.

Although the Complaint does not specifically address the violation of ERISA, Plaintiffs

concede that this case and Aetna's plan, in this case, is governed by ERISA and Aetna's conduct violates ERISA. The thrust of the Motion is the contention that Aetna utilized a number of factors in determining whether a medical procedure, like PRP injections, is "experimental and investigational." On this point, Aetna relies upon its own Clinical Policy Bulletin for Blood Product Injections for Selected Indications. Def. Mem., Exhibit B. The Clinical Policy Bulletin quotes several case studies wherein the improvement rate of patients who had been administered PRP injections was compared to the improvement rate of patients who had not. Interestingly, several of the studies revealed that patients who had been given a PRP injection healed at an exponentially faster rate. For example, Allan Mishra, MD and Terri Pavelko, PAC, PT performed a study involving patients with elbow tendonosis, which produced the following findings and conclusions:

Subjects were initially given a standardized physical therapy protocol and various non-operative treatments. Eight weeks after treatment, the PRP injected patients noted a 60% improvement in their VAS versus 16% in bupivaccine-treated patients. At 6 months, PRP-treated subjects noted an 81% improvement in their VAS. At final follow-up, the PRP-treated patients reported a 93% reduction in pain compared with before the treatment.

Treatment of patients with chronic elbow tendonosis with buffered platelet-rich plasma reduced pain significantly in this pilot investigation...Finally, platelet-rich plasma should be considered before surgical intervention.

Mishra A., Pavelko T., Treatment of chronic elbow tendonosis with buffered platelet-rich plasma. Am J Sports Med. 2006; 34(11): 1774-1778.

JC Peerbooms and his associates performed a case study with patients suffering from chronic lateral epicondylitis, wherein half the patients were given a PRP injection while the other half was given a corticosteroid. The findings and conclusions were:

Successful treatment was defined as more than a 25% reduction in VAS or DASH score without a re-intervention after 1 year. The results showed that according to the VAS, 24 of the 49 patients (49%) in the corticosteroid group and 37 of the 51 patients (73%) in the PRP group were successful, which was significantly different. Furthermore, according to

the DASH scores, 25 of the 49 patients (51%) in the corticosteroid group and 37 of the 51 patients (73%) in the PRP group were successful, which was also significantly different. The corticosteroid group was better initially and then declined, whereas the PRP group progressively improved.

Treatment of patients with chronic lateral epicondylitis with PRP reduces pain and significantly increases function, exceeding the effect of corticosteroid injection.

Peerbooms J.C., Sluimer J., Bruijn D.J., Gesens T., Positive effect of an autologous platelet concentration in lateral epicondylitis in a double-blind randomized control trial: Platelet-rich plasma versus corticosteroid injection with a 1-year follow-up. *Am J Sports Med.* 2010; 38(2): 255-262.

The studies mentioned above most closely resemble the case in dispute as they deal with a tendon injury and PRP injections being utilized as opposed to surgical intervention. The remaining studies, relied upon by Defendant, involve bone and/or cartilage related ailments or involve patients who underwent surgery. Moreover, none of the case studies relied upon by Defendant involve PRP injections administered for a shoulder injury.

A fundamental issue exists regarding the conveniently, albeit strategically, selected studies involving patients and/or injuries that are unrelated to the injury sustained herein as a basis for Aetna's policy of denying outright PRP injections. Moreover, the most analogous studies to the case at bar completely contradict the contention that PRP injections are experimental and have not been proven effective.

Platelet-Rich Plasma grew from its promise as a safe and natural alternative to surgery. It involves extracting a patient's own blood and placing it in a centrifuge where the blood spun to create a concentration of platelets above the body's normal baseline. The concentration of platelets is then injected into the injury site. Studies suggest that platelets contain an abundance of growth factors and cytokines that can affect inflammation, postoperative blood loss, infection, osteogenesis, wound, muscle tear and soft tissue healing. (Guidelines for the Use of Platelet Rich Plasma: The International Cellular Medical Society). Research now shows that platelets also

release many bioactive proteins responsible for attracting macrophages, mesenchymal stem cells and osteoblasts that not only promote removal of degenerated and necrotic tissue, but also enhance tissue regeneration and healing. (Guidelines for the Use of Platelet Rich Plasma: The International Cellular Medical Society). For approximately 20 years, musculoskeletal practitioners have used PRP to treat tendinopathy, and despite that fact, Aetna's policy is to deny requests for reimbursement "across the board" for such procedures. Plaintiff was obliged to pursue a multi-level appeals procedure, and informed at each step of the process that Aetna was denying the claim on the ground that PRP injections are "experimental." Notwithstanding this process, Plaintiff has provided a detailed basis for the explanation and acceptance of PRP injections as a valid acceptable procedure in the medical community. As such, the policy deeming the PRP injections "experimental and investigational" is arbitrary and capricious.

RESPONSE TO STATEMENT OF MATERIAL FACTS

1. Admitted.
2. Admitted.
3. Admitted to the extent the Plan speaks for itself. Denied that Aetna has discretion beyond the confines of ERISA to make determinations.
4. Admitted to the extent the Plan speaks for itself.
5. Admitted to the extent the Plan speaks for itself.
6. Admitted to the extent the Plan speaks for itself.
7. Admitted that the Plan speaks for itself. Notwithstanding same, the determination regarding whether PRP injections are experimental and investigational requires more than a cursory medical opinion from selective medical journal articles.
8. Admitted to the extent the Plan speaks for itself.
9. Admitted to the extent the Plan speaks for itself.
10. Denied. Some of the article cited by Defendant support the efficacy and use of PRP. (Mishra A., Pavelko T., Treatment of chronic elbow tendonosis with buffered platelet-rich plasma. Am J Sports Med. 2006; 34(11): 1774-1778.) (Peerbooms J.C., Sluimer J., Bruijn D.J., Gesens T., Positive effect of an autologous platelet concentration in lateral epicondylitis in a double-blind randomized control trial: Platelet-rich plasma versus corticosteroid injection with a 1-year follow-up. Am J Sports Med. 2010; 38(2): 255-262.)
11. Admitted.
12. Admitted.
13. Admitted to the extent the Plan speaks for itself.
14. Admitted to the extent the Bulletin speaks for itself.
15. Admitted to the extent the Bulletin speaks for itself.
16. Denied. The CPB fails to consider the medical efficacy detailed in several articles. (Mishra A., Pavelko T., Treatment of chronic elbow tendonosis with buffered platelet-

rich plasma. Am J Sports Med. 2006; 34(11): 1774-1778.) (Peerbooms J.C., Sluimer J., Bruijn D.J., Gesens T., Positive effect of an autologous platelet concentration in lateral epicondylitis in a double-blind randomized control trial: Platelet-rich plasma versus corticosteroid injection with a 1-year follow-up. Am J Sports Med. 2010; 38(2): 255-262.)

17. Admitted to the extent that the document speaks for itself, however, which services are considered “experimental or investigational” is at issue in this case.
18. Admitted to the extent that the document speaks for itself, however, which services are considered “experimental or investigational” is at issue in this case.
19. Admitted.
20. Admitted.
21. Admitted.
22. Admitted.
23. Admitted.
24. Admitted with the exception of the characterization of the “bald assertions.”
25. Admitted.
26. Admitted.
27. Admitted.
28. Admitted.
29. Admitted.
30. Admitted.
31. Denied. See response to Numbers 10 and 16, above.
32. Admitted.
33. Admitted. However, Dr. Lambert set forth the basis for the medical benefit to the patient in his letter.
34. Admitted.

35. Admitted.

36. Denied. The appeal disputed the characterization of PRP injections as experimental and investigational.

37. Admitted.

38. Admitted.

LEGAL ARGUMENT

I.

SUMMARY JUDGMENT STANDARD

Pursuant to Rule 56(c), summary judgment is proper only if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). "A factual dispute is material if it bears on an essential element of the plaintiff's claim, and is genuine if a reasonable jury could find in favor of the nonmoving party." Natale v. Camden County Correctional Facility, 318 F.3d 575, 580 (D.N.J. 2003). The moving party has the initial burden of informing the court of the basis for its motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. In reviewing the record, the court is "required to view the inferences to be drawn from the underlying facts in the light most favorable to [the non-moving party]." Kopec v. Tate, 361 F.3d 772, 775 (3d Cir. 2004). The non-moving party's allegations must be taken as true "when supported by proper proofs whenever these allegations conflict with those of [the moving party]." Id. The motion should only be granted if, "viewing the evidence in the light most favorable to the nonmoving party, there is no question of material fact for the jury and any verdict other than the one directed would be erroneous under the governing law." Beck v. City of Pittsburgh, 89 F.3d 966, 971 (3d Cir. 1996) (internal quotations omitted).

II.

THE COMPLAINT STATES CLAIMS UNDER ERISA

A. The Facts Show that Aetna Has Acted in Violation of ERISA

Under ERISA 502(a)(1)(B):

(a) A civil action may be brought

(1) by a participant or beneficiary

(B) to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan 29 U.S.C. § 1132(a)(1)(B).

The standard needed to establish a claim against the ERISA governed health plans is whether the determination to deny reimbursement was arbitrary and capricious. A plan administrator's decision is arbitrary and capricious if "it is clearly not supported by the evidence in the record or the administrator has failed to comply with the procedures required by the plan." Orvosh v. Program of Group Ins. For Salaried Employees of Volkswagen of Am. Inc., 222 F.3d 123, 129 (3d Cir. 2000).

The Complaint alleges that Aetna improperly denied reimbursement for PRP injections, despite the fact that said procedure was properly prescribed and performed, and ample literature exists indicating that PRP is an effective, non-experimental medical procedure. (Complaint ¶12) The Complaint sets forth that the Plaintiff provided the facility wherein PRP injections were administered for T.S., received an assignment of benefits from the patient, submitted requests for reimbursement to Aetna, and were denied on the ground that PRP injections supposedly were "experimental." In this case, the Plaintiff followed the multi-stage appeals process dictated by Aetna through to a fruitless end. Plaintiff seeks damages comprised of the benefits improperly

denied and the unnecessary administrative and legal costs imposed on providers and patients pursuing a preordained result. See, e.g., Pennsylvania Chiropractic Assoc. v. Blue Cross Blue Shield Assoc., 2010 WL 1979569, at *25 (N.D.Ill. May 17, 2010) (declining to dismiss ERISA claims brought by chiropractic health care providers alleging that insurance companies maintained an improper practice of demanding recoupment, on fraudulent pretexts, of reimbursements paid to the providers.)

Aetna's entire basis for denying the PRP injections is based upon its blanket policy of denying this medical procedure regardless of the efficacy and medical benefit to the patient. In short, Aetna would never permit payment of this medical procedure as a matter of course under any circumstance. The entire rationale behind this Policy (Def. Mem, Exhibit B) is derived from a few strategically selected medical case studies involving patients with dissimilar injuries and differing levels of medical treatment. Based upon the extensive medical literature and the acceptance of PRP injections in the medical community, Aetna's decision to deny payment in this matter is unreasonable.

B. Defendant Never Reached the Issue of Medical Necessity For the PRP Injections

Aetna never addresses the medical necessity of T.S.'s medical treatment since they erect a barrier by deeming PRP injections in general as experimental and investigational. Aetna never provided a medical review of necessity for T.S., and it is long past the time permitted to do so. See 29 CFR Part 2560 (Nov. 10, 2000) at p. 70267 ("the plan administrator shall notify the claimant...of the plan's adverse benefit determination within a reasonable period of time, but not later than 30 days after receipt of the claim.").

Aetna argues that the denials of reimbursement were not arbitrary and capricious to the extent the denials were made on the ground that PRP injections are "experimental," but not to the

extent that the denials were made on any other “independent grounds.” (Def. Mem. at 14-15). In fact, the theory propounded in the Complaint is not merely that Aetna’s reliance on the ground that PRP is “experimental” in denying coverage is arbitrary and capricious, but that Aetna wholly ignores that medical necessity of the PRP injections for this patient. The fact that the specific records of T.S. are not reviewed or taken under consideration speaks to the manner in which Aetna’s policy is arbitrary and capricious. Because Aetna’s blanket policy of denial is determinative in every PRP case, and further analysis is foreclosed, there simply were no other “independent grounds” for Aetna’s coverage decisions. Aetna attempted to justify its systematic denials with the indefensible contention that PRP injections are *per se* experimental.

The holding of DeVito v. Aetna, Inc., 536 F. Supp. 2d 523 (D.N.J. 2008), is instructive here. In DeVito, Judge Hochberg refused to dismiss a complaint alleging that the insurance company had a policy of refusing to pay for treatments for eating disorders, allegations that are extremely similar to those herein. As Judge Hochberg explained her ruling:

Although Defendants argue that ‘[n]either the Mental Health Parity Law nor the SEHB plans allow Aetna to presume all treatment for BBMI or non- BBMI is ‘medically necessary,’ this is immaterial to the present motion. Plaintiffs do not allege that Defendants are required to find all treatment for eating disorders ‘medically necessary.’ Rather, Plaintiffs allege that Defendants’ denial of claims on grounds that the treatment was ‘not medically necessary’ was pretextual. Plaintiffs allege that Defendants have improperly denied some claims as ‘not medically necessary’ because of Defendants’ policy of denying all such claims in violation of the terms of Plaintiffs’ contracts. Whether Plaintiffs’ pretext allegations are true or false is an issue that will be determined when the case reaches the merits stage. 536 F. Supp. 2d at 532 n.7.

Judge Hochberg also found sufficient plaintiffs’ allegations that the appeal process was an exercise in futility, at least for the purposes of a Rule 12(b)(6) motion. Id at 532.

Plaintiffs urge the Court to adopt the DeVito reasoning in this case. This case illustrates that Horizon rejects PRP claims as a matter of routine without any individualized assessment of

medical necessity. T.S. received PRP injections for an injury to his right shoulder. Aetna initially denied reimbursement, stating that the PRP injections were services Aetna determined were not effective and therefore they were not covered. T.S.'s medical records were then submitted to Aetna with a first-level appeal of the denial, along with a letter detailing the case and explaining why the procedures were medically necessary/effective. Aetna denied the appeal, stating "Services described by code(s) 0232T are not eligible for payment. Aetna considers the use of platelet-rich plasma, alone or in conjunction with bone grafting materials, experimental and investigational..." This makes clear that Aetna was not grounding its denial on any individualized analysis of T.S.'s case for medical necessity, but rather on a blanket policy of denying PRP claims.

Aetna relies upon several cases, including but not limited to, Advanced Rehab, LLC v. United Health Group, Inc., 2012 U.S. App. LEXIS 20050 (3d Cir. September 25, 2012). However, none of the cases cited by Defendant involve PRP injections. Defendant's reliance on the cited case law is misplaced and its determination that PRP injections are experimental and investigational was arbitrary and capricious.

CONCLUSION

Based upon the foregoing, Plaintiffs respectfully submit that Defendant's Motion for Summary Judgment should be denied.

MASSOOD & BRONSICK, LLC
Attorney for Plaintiffs



By: _____
ANDREW R. BRONSICK

Dated: March 4, 2013